Subcommittee on Criminal Justice, Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

"Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards"

June 27, 2006

Good afternoon and thank you all for being here.

We are here today to discuss the findings and recommendations of a GAO report requested by Mr. Cummings, the Ranking Member of this Committee, Senator Grassley, and myself.

We asked the GAO to investigate oversight of clinical labs and implementation of quality requirements imposed through CLIA, the Clinical Laboratory Improvement Amendments of 1988. In particular, we requested that GAO assess the quality of lab testing and the adequacy of CLIA oversight.

Lab testing is a vital link in our nation's healthcare system. Lab tests affect an estimated 70 percent of medical decisions, and are one of the most frequently billed Medicare procedures. Accurate results are necessary for determining proper treatment of patients, while erroneous results can lead to the wrong treatment decisions with potentially detrimental effects for the patients, and quite possibly unnecessary mental anguish.

The resulting report by the GAO, *Clinical Lab Quality: CMS and Survey Organization Oversight Should be Strengthened,* is a sobering evaluation of the current state of clinical labs oversight, and the quality assessment deficiencies that exist across the country for monitoring the nation's 193,000 labs.

Our request to the GAO was prompted by problems at Maryland General Hospital that came to light in 2004. Maryland General Hospital's lab issued more than 450 questionable HIV and hepatitis test results. College of American Pathologists, or CAP, inspected and accredited Maryland General Hospital during the 14-month period that the lab was issuing the questionable results; CAP's inspections failed to identify the ongoing deficiencies in lab testing at the Maryland General facility.

The Maryland General situation was compounded by numerous problems and deficiencies in reporting and evaluation of the lab, prompting this Subcommittee, at the request of Mr. Cummings, to hold two hearings to investigate the issues that led to the deficiencies at Maryland General Hospital, and how these problems went undetected and un-addressed for such a long period of time.

The Subcommittee was concerned then, as it is now, that a similar situation might repeat itself at other hospitals or labs in other parts of the country.

Today's release of the GAO report demonstrates that there are several areas where clinical lab quality oversight by the Centers for Medicare and Medicaid Service is deficient. The problems

flagged by the GAO show quite clearly that despite CMS's responsibility for overseeing the quality of our nation's labs, there is insufficient data for measuring the seriousness or extent of problems.

While the responsibility for ensuring lab quality ultimately lies with CMS, lab survey and accreditation is handled largely by independent, national accrediting organizations; 97% of all accredited labs are surveyed by three accrediting organizations, each of which has representatives here to testify today: the College of American Pathologists (CAP), COLA, formerly known as the Commission on Office Laboratory Accreditation, and the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO. Two states, New York and Washington, are CLIA-exempt, but have state survey programs.

Each of the survey organizations measure labs using standards that CMS has determined are at least equivalent to CLIA standards; and the survey organizations are required to conduct complaint investigations and monitor proficiency test results.

In theory, this arrangement should ensure that accredited labs have been inspected on a reasonable, periodic basis, and found to meet CLIA standards. Nonetheless, GAO found that in contemporary practice, it is impossible to get a true picture of lab quality standards.

Among the problems flagged by the GAO and which we'll explore today are:

- survey organization standards are not standardized with CLIA requirements, making it impossible to measure lab quality nationwide in a standardized manner;
- lab quality deficiencies may not be reported due to accrediting agencies' emphasis on education over enforcement;
- whistle-blower protections don't exist for all survey organizations, including COLA, which does not have a formal whistle-blower policy;
- lab sanctions are rarely imposed – in fact, out of more than 9000 labs that had sanctions proposed, only 501 labs were actually sanctioned by CMS from 1998-2004.

Despite the fact that there is a solid framework for what I believe should be a workable system to ensure lab quality, GAO has found that in current practice, the oversight by CMS is deficient, making it impossible to accurately measure the effectiveness of independent survey organizations.

Today's hearing will explore GAOs findings and recommendations, and give CMS and survey organizations an opportunity to present ways to improve the current situation so that what happened at Maryland General Hospital does not repeat itself anywhere else in the country.

Our first witness is Leslie Aronovitz, Director of the Health Division, U.S. Government Accountability Office; We'll then hear from Mr. Thomas Hamilton, Director of the Survey and Certification Group at the Centers for Medicare and Medicaid Services.

Our second panel will include Dennis S. O'Leary, M.D., President of the Joint Commission on Accreditations of Healthcare Organizations; Doug Beigel, Chief Executive Officer of COLA, and Thomas Sodeman, M.D., President of the College of American Pathologists.

Thank you all for being here today. We look forward to your testimony and insights.